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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/457,864	12/10/99	BULLA L	27112000371S

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EXAMINER	
KAUFMAN, C	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/457,864	BULLA, LEE A.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed 9/02/01 has been entered.

The CRF submitted 8/2/01 has been entered with the following correction made by the USPTO STIC staff: non-ASCII "garbage" at the beginning/end of the files has been deleted. Notice of this correction is provided for Applicant's information, and no action by Applicant is necessary.

When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and a sequence identifier ("SEQ ID NO:X") must be used either in the drawing or in the Brief Description of the Drawings. See MPEP § 2422.02. In the instant application, a sequence identifier must be used for the sequences appearing in Figure 2I. The Brief Description of Figure 2I does not account for all sequences present. Each sequence must have its own unique sequence identifier and be listed in the CRF and paper copy of the Sequence Listing.

Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: The amendment to page 5, line 20, appears to have a typographical error in the form of an underline in "No:2" in the second line of the amendment.

Appropriate correction is required.

Claim Objections

Claims 4, 8 and 15 are objected to because of the following informalities: there is no article in front of "eukaryotic cell". This can be corrected by adding "said" before "eukaryotic". Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-15 are rejected under the judicially created doctrine of double patenting over claims 5-10 of U. S. Patent No. 5,693,491 (of parent application 08/326,117) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both claim a method of producing a BT-toxin receptor, with the patented claims being more narrowly drawn to producing a naturally occurring receptor; however the species anticipates the genus.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 13-15 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for methods wherein the expressed BT toxin receptor is one that (1) is encoded by a polynucleotide encoding a receptor that has an amino acid sequence of the receptor shown in SEQ ID NO:2 (2) has the same sequence as an insect BT toxin receptor that occurs in nature and is encoded by a polynucleotide that hybridizes under conditions comprising any one of those listed on page 13, lines 4-12 (see rejection under 112, second paragraph, below) to the full-length cDNA nucleotide sequence of SEQ ID NO:1, or (3) is encoded by a polynucleotide that hybridizes under one of the above conditions to the full-length cDNA nucleotide sequence of SEQ ID NO:1, and which BT toxin is cryAI(b), (see patented claims 16 and 5-8 in US Patent 5,693,491), or a fragment of any one of BT toxin receptors of (1)-(3) which comprises at least 234 amino acids of the C-terminus, does not reasonably provide enablement for methods requiring an encoded BT toxin receptor other than the above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Enablement is not commensurate in scope to practice claims 1, 5 and 13 and their dependent claims. The claims are to methods that require a polynucleotide encoding a BT toxin-binding receptor, which does not have to have the sequence of a protein which occurs in nature. Yet no such polynucleotide is disclosed in the prior art and the specifications discloses only one, which encodes a naturally occurring receptor and has been shown to bind only a single BT toxin. There are no disclosures of polynucleotides which encode non-naturally occurring proteins and bind a BT toxin. Further there are many types of BT toxins (*e.g.*, cryAI(a), -(b), -(c), cryIIIA, and cryIVD) described in the prior art. However, the scope of the claims encompasses a protein which is not naturally occurring and encoded by a polynucleotide that hybridizes under

conditions of standard stringency to the polynucleotide with the nucleotide sequence shown in Figure 1, which hybridization conditions allow for great sequence difference between SEQ ID NO:1 and the hybridizing polynucleotide so there is little structural similarity required between the hybridizing polynucleotides.

Also, sections d) and h) of claims 1 and 5 and section d) of claim 13 recite a fragment of a BT-toxin receptor that is encoded by a nucleic acid that hybridizes to SEQ ID NO:1 and binds and unspecified BT toxin. It is not disclosed in the parent application or prior art which portion(s) or amino acids of a known BT toxin receptor are necessary for toxin binding. The instant specification discloses only that a fragment comprising the last 234 C-terminal amino acids is necessary and sufficient for binding paragraph bridging pages 36-37). This situation is further complicated by the fact that a single BT toxin appears to have different regions required for the binding of the toxin to a BT toxin receptor from different insect species (U, Oddou et al., Eur. J. Biochem., 212:145-150, 1993, see p. 145, col. 2, end of first paragraph). It is acknowledged that the skill in the receptor and molecular biology arts is high; however, skill in the BT toxin receptor art is not because of the paucity of known receptors which bind any one of the many known BT toxins and the disclosure of only one encoding polynucleotide sequence and one complete amino acid receptor sequence (both disclosed in the instant specification), though such receptors had been long sought for, and so little was know about such receptors. Because of the absence of guidance in the instant application, lack of information in the prior art, and breadth of the encoded receptors encompassed in the claims, one could not predict what structural features the amino acid sequence of the receptor or encoding polynucleotide would need to possess for binding to a BT toxin to occur. For the reasons set forth, it would require undue experimentation to practice the claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 13 and dependent claims 2-4, 6-8 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5 and 13 are indefinite because what is meant by "high stringency" conditions of hybridization is unclear. There is no single art recognized definition of "high stringency". It is not clear what the intended hybridization parameters are meant to be. This rejection could be obviated by specifying in the claims the parameters (*e.g.*, temperature during hybridization, salt conc., *etc.*, and wash) of hybridization conditions to eliminate ambiguity. While the specification has examples of stringent hybridization (13, lines 4-12), examples are not limiting.

Claims 1 and 5 recite cells in sections a)-d), however, the claims are indefinite because it is not clear if the encoded receptor is expressed. The claims are incomplete for omitting an essential step, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps is: expression of the encoded receptor so that binding may occur.

Claim 13 is indefinite because on page 41, line 16 (third to last line of the claim), it is unclear if "said nucleic acid" is the encoding nucleic acid or the nucleic acid of SEQ ID NO:1. It is suggested that substitution of the term polynucleotide for one specific group of nucleic acids, with consistent use of each term, could obviate this rejection.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note that while the prior art does disclose methods of determing whether an agent binds, *e.g.*, Vadlamudi et al. (J. Biol. Chem. 1993, cited by Applicants), the prior art does not disclose such methods in which an encoding nucleic acid was used. As of the effective filing date of the instant application for a nucleic acid encoding a BT toxin receptor, no such nucleic acid had been taught in the prior art.

Conclusion

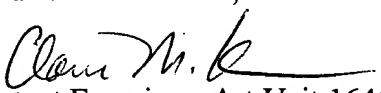
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

September 10, 2001